



UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM41/0831

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/943,546	10/03/97	020	JAWORSKI, E	3737 08/31/98
First Named Applicant	AVERKIOU, NICHALAKIS			

TITLE OF INVENTION

ULTRASONIC DIAGNOSTIC IMAGING OF RESPONSE FREQUENCY
DIFFERING FROM TRANSMIT FREQUENCY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 ATL150	600	447,000	142 UTILITY	NO	\$1320.00	11/30/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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11

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

- ☒ This communication is responsive to Amendment 8/26/98
- ☒ The allowed claim(s) are 1-16, 39-42
- ☐ The drawings filed on _____ are acceptable.
- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☒ Applicant MUST submit NEW FORMAL DRAWINGS
- ☒ because the originally filed drawings were declared by applicant to be informal.
- ☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____
- ☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.
- ☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

- ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- ☒ Notice of References Cited, PTO-892 1 sheet
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5, 7, 9
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Interview Summary, PTO-413
- ☐ Examiner's Amendment/Comment
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Examiner's Statement of Reasons for Allowance

Francis J. Jaworski
Primary Examiner

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1. The following changes to this application have been enacted:

Claims 17-38 and 43-47 have been cancelled.

The following is an examiner's statement of reasons for allowance:

An evaluation of the claims language of the August 26th amendment versus the prior art was made with the following distinctions in mind. Non-linear effects of propagated ultrasound within the living body may be studied in relation to imaging but with purposes other than enhancing an image or providing a harmonic image, to wit purposes such as patient safety during conventional imaging at higher powers (or during kinesitherapy or diathermy), evaluation of the degree of distorting effects on conventional B-mode images, evaluation of energy losses due to increased attenuation of the developed harmonic content relative to the transmission fundamental, and/or with the purpose of minimizing those losses such as by compensating for main lobe level reduction for 'robbed' energy or for example by deciding upon transmission power levels for contrast agent perfusion Doppler study such that a tissue harmonic effect becomes negligible in relation to contrast agent effect. The studies may also not involve an imaging process but rather a

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one-dimensional measurement, for example a uni-valued B/A measurement or a temporal scalar pertaining to a harmonic of myocardial phase, they may be in vitro on excised tissue or in simulation upon a phantom, they may be through-transmission and not reflective and they may not involve the measurement of a true tissue harmonic response, meaning that for one example the high level ultrasound destruction of tissue causes cavitation destruction which yields chaotic harmonic generation; for another example microbubble harmonic generation arises locally due to a resonance effect of the ensonating pressure wave and neither is fairly characterizable as a bona fide tissue harmonic response. The tissue harmonic itself may not be spatially imaged as a result but rather a dimensionless B/A quantity may be produced or the tissue harmonic may be acknowledged to be present as a residue or baseline contaminant in an image adapted to display microbubble harmonic content. The ensonating transducer system also may be unfocussed or incapable of selective focussing so as to exert any control over energy density with depth.

Applicant's invention is believed to reside inter alia in the recognition that multipath clutter and the self-deteriorating effects on resolution due to saturation of the medium by phase velocity distortion of the sine wave and accelerated attenuation in the emerging harmonic components due to the higher attenuation at the harmonic frequency which occur during the dynamic event of passage of the ensonating beam to its target may be mitigated by adapting the transmit controller to provide array element ensonating beam components below the tissue non-linear response threshold in the near-field of the array.

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When the various literature and patent submissions are critically evaluated for the initially mentioned shortcomings, **Ward et al** (1995, 1997 of record), **Williams** (WO 91/15999) and **Christopher** (PCT/US97/20162, of record) remain insofar as they fairly pertain to bona fide pulse echo tissue harmonic imaging. Reviewing these documents: Ward et al use a fixed focus circular transducer which delivers an initial energy concentration such that the harmonic generation process with attendant self-deteriorating effects as outlined in Muir et al 1980 Fig. 1 begins at the sample entry point such that multi-path clutter results and is not corrected. Williams page 7 makes the suggestion that one operating mode of this (in the main microbubble harmonic contrast/harmonic Doppler imager) system would be a two-pulse method in which the fundamental or harmonic signal from the tissue volume before contrast agent administration would be subtracted from the harmonic signal after contrast agent administration but invokes that conventional transducer components be used. Christopher, assuming arguendo that the 11/8/96 filing date be applicable, mentions using a phased array to vary the focal point within a generally flat sample specimen understood to include breast and abdominal wall layers and within the general context of an imaging discussion. None of the prior art, alone or in combination teaches or suggests controlling the transmit wave components of the array elements of the harmonic imager to have insufficient energy to stimulate significant harmonic responses in the near field as opposed to focussing to a higher (harmonic-stimulatory) level at greater depths nearer to the target region, Ward et al 1995 page 965 noting in contrast that modern ultrasound scanning

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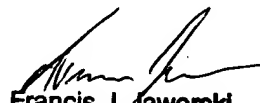
systems such as may be inferred to provide the equipment conventionalities called for in the references reach non-linear effect level ranges during conventional use.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication should be directed to Examiner Francis J. Jaworski at telephone number (703) 308-3061.

FJJ:fjj

8-27-98


Francis J. Jaworski
Primary Examiner